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| 10/021,633      | 12/12/2001  | Richard John Booth   | 5822-P1-01-CA       | 9641             |

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WARNER-LAMBERT COMPANY  
2800 PLYMOUTH RD  
ANN ARBOR, MI 48105

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| EXAMINER |
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MORRIS, PATRICIA L.

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1625     | 70           |

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

|                 |            |                |             |
|-----------------|------------|----------------|-------------|
| Application No. | 10/021,633 | Applicant(s)   | Booth et al |
| Examiner        | P. Morris  | Group Art Unit | 1625        |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

Responsive to communication(s) filed on 3/24/03.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

Claim(s) 1 - 44 is/are pending in the application.

Of the above claim(s) 3, 8-11, 14, 17, 18 and 21-44 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1, 2, 4-7, 12, 17, 15, 16, 19 and 20 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892

Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948

Other \_\_\_\_\_

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**DETAILED ACTION**

Claims 1, 2, 4-7, 12, 14, 15, 16, 19 and 20 are under consideration in this application.

Claims 3, 8-11, 14, 17, 18 and 21-44 are held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b)

*Election/Restriction*

Applicant's election without traverse of Group I in Paper No. 9, filed March 24, 2003 is acknowledged.

Applicants will only be entitled to species readable on the **elected** species. Examination has been expanded to include the genus set forth below. The instant compounds are well known in the prior art as evidenced by the prior art. The prior art of record is just a sampling of the prior art.

It is too burdensome for the examiner to search all of the previously noted searches in their respective, completely divergent, areas for the non-elected subject matter, as well, in the limited time provided to search one invention.

The restriction requirement is deemed sound and proper and will be maintained.

This application has been examined with regard to the elected compounds wherein R<sup>1</sup> represents pyridyl and substituted pyridyl, R<sup>2</sup> represents phenyl and substituted phenyl, R<sup>3</sup> represents phenyl, substituted phenyl and biphenyl and n is 0-2, exclusively.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(f) he did not himself invent the subject matter sought to be patented.

Claims 1, 4, 6, 7, 19 and 20 are rejected under 35 U.S.C. 102(a), (b) (e) and/or (f) as being anticipated by Daines (WO 98/09630), Wagner et al. (US 5,453,432), Deyanov et al. (CA 115:279952), Kester et al. (US 4,855,308), Barchiesi et al. (CA 108:130898), Moerkved (CA 106:156246), Shramm et al. (CA 102:166694), Ferranti et al. (CA 102: 149072), Abramovitch et al. I (J. Org. Chem. 1983, 48, 4391-4393), II (CA 92:146559), III (J. Org. Chem., 1974, 39, 1795-1802), IV (CA 84:74053), V (J.Org. Chem., 1974, 39, 1802-1807), VI (US 3,624,096) Peterson et al. (CA 95:169072), Shell (CA 95:97849) and Aries (Fr 7699).

Daines specifically recites the instant compounds wherein R<sup>1</sup> represents pyridyl, R<sup>2</sup> represents substituted phenyl, R<sup>3</sup> represents phenyl and n is zero. Note example 12 therein.

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Wagner et al., Peterson et al. and Abramovitch et al. III, IV, VI recite the instant compounds wherein  $R^1$  represents substituted pyridyl,  $R^2$ ,  $R^3$  represents phenyl and  $n$  is zero. Note compound no. 11 of Wagner et al. or RN's 79441-19-3, 79441-21-7, etc., of Peterson et al. or RN 73295-34-8 of Abramovitch et al. II or etc., RN's 58254-73-2, 58254-70-9, etc., of Abramovitch et al. IV.

Deyanov et al., Shramm et al. and Abramovitch et al. I disclose the claimed compounds wherein  $R^1$  represents substituted pyridyl,  $R^2$  represents phenyl,  $R^3$  represents phenyl and substituted phenyl and  $n$  is zero. Note RN's 137549-49-6, 137549-50-9, etc of Deyanov et al. or the compounds recited in Table I of Abramovitch et al. I.

Kester et al. recite the instant compounds wherein  $R^3$  represents substituted phenyl,  $R^2$  represents phenyl,  $R^1$  represents pyridyl and  $n$  is zero. Note example 34 therein.

Barchiesi et al., Abramovitch et al. V and Moerkved recite the claimed compounds wherein  $R^1$  represents pyridyl,  $R^2$ ,  $R^3$  represents phenyl and  $n$  is zero. Note RN's 32967-16-1 and 73333-84-3 of Barchiesi et al. or the compounds in Table I of Abramovitch et al. V.

Ferranti et al. and Aries specifically disclose the instant compounds wherein  $R^1$  represents substituted pyridyl,  $R^2$ ,  $R^3$  represents substituted phenyl and  $n$  is zero, Note RN 95729-19-4 of Ferranti et al. or examples 13-16, etc., of Aries et al.

Shell recites the claimed compounds wherein  $R^1$  represents pyridyl,  $R^2$ ,  $R^3$  represents phenyl or substituted phenyl and  $n$  is one. Note RN's 78675-28-2, 78675-37-3, etc.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4-7, 12, 14, 15, 16, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Daines, Wagner et al., Deyanov et al., Kester et al., Barchiesi et al., Moerkved, Shramm et al., Ferranti et al., Abramovitch et al I-VI, Peterson et al., Shell and Aries.

As discussed *supra*, the references disclose the instant compounds.

It is believed that one having ordinary skill in the art would have found the claimed compounds *prima facie* obvious, since they are generically embraced by the disclosed formula; In

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re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). See also In re Malagari, 499 F.2 1297, 182 USPQ 549 (CCPA 1974); In re Lemin, 332 F.2d 839, 141 USPQ 814 (CCPA 1964); In re Rosicky, 276 F.2d 656, 125 USPQ 341 (CCPA 1960). The requisite motivation for arriving at the claimed compounds stems from the fact that they fall within the generic class of compounds disclosed by the references. Accordingly, one having ordinary skill in the art would have been motivated to prepare any of the compounds embraced by the disclosed generic formula, including those encompassed by the claims.

It is believed well settled that a reference may be relied upon for all that it would have reasonably conveyed to one having ordinary skill in the art. In re Fracalossi, 681 F.2d 792, 215 USPQ 569 (CCPA 1982); In re Lamberti, 545 F.2d 747, 192 USPQ 278 (CCPA 1976); In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); In re Susi, supra.

Further, the prior art compounds differ from the compounds claimed herein as position isomers, halogen analogs and alkyl homologs of the claimed compounds. For example, the instant compounds wherein n is two are but the next adjacent homologs of the compounds of Shell or the compounds wherei the pyridyl is substituted by ethyl are but the next adjacent homologs of Deyanov et al. One having ordinary skill in the art would have been motivated by the disclosure of the prior art compounds to arrive at other compounds within the claimed genus as well as at the claimed species. The motivation to make these compounds is their close structural similarities to the disclosed compound. While homology is considered to be present even if true "homology" is not present, such does not defeat the *prima facie* case of obviousness raised by the art.

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Attention, in this regard is directed to In re Druey et al., 50 CCPA 1538, 319 F.2d 237, 138 USPQ 39, wherein Judge Worley, delivering the Court's opinion, stated:

"We need not decide here whether the compounds in question are properly labeled homologues. It appears to us from the authorities cited by the solicitor and appellants that the term homologue is used by chemists at times in a broad sense, and at other times in a narrow or strict sense. The name used to designate the relationship between the related compound is not necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new compound." 50 CCPA 1541.

Also, as the Court stated in In re Payne et al., 606 F.2d 302, 203 USPQ 245 at 255 (CCPA 1979):

"the name used to designate the relationship between related compounds is not necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new compound."

In addition, any question of why would one conceive and use the similar compounds (*i.e.* "motivation") is answered by the Court in In re Gyurik et al., 596 F.2d 1012, 201 USPQ 552 at 557.

"In obviousness rejections based in close similarity in chemical structure, the necessary motivation to make a claimed compound, and thus the *prima facie* case of obviousness, rises from the expectation that compounds similar in structure will have similar properties."

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 6, and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The expression "substituted" is employed in claims 1, 5, 6 and 7 with no indication given as to what the substituents and protective groups really are.

One should be able, from a reading of the claims, determine what that claim does or does not encompass.

Why? Because that claim precludes others from making, using, or selling that compound for 20 years. Therefore, one must know what compound is being claimed.

Where is, what is intended by applicant, supported in the specification with sufficient representative exemplification. Note United Carbon Co., v. Binney Smith Co., 55 USPQ 381, Supreme Court of the United States (1942) "an invention must be capable of accurate definition, and it must be accurately defined to be patentable", above at page 386.

The unknown substitution groups are not believed to meet the requirements of 35 USC 112, first paragraph. These unknown substituents could easily alter the utility.

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The written description is considered inadequate here in the specification. Conception of the intended substituents should not be the role of the reader. Applicants should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 USC 112, first paragraph. If you (the public) find that it works, I claim it, is not a proper basis of patentability.

In re Kirk, 153 USPQ 48, at page 53.

The claims measure the invention. United Carbon Co. V. Binney & Smith Co., 55 USPQ 381 at 384, col. 1, end of 1st paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in Lockheed Aircraft Corp. v. United States, 193 USPQ 449, "Claims measure invention and resolution of invention must be based on what is claimed".

The C.C.P.A. in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant. We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": In re Priest, 199 USPQ 11, at 15.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 19 and 20 are an extension or substantial duplicates of the compounds. By adding the expression "in admixture with a pharmaceutically acceptable carrier" would overcome this rejection.

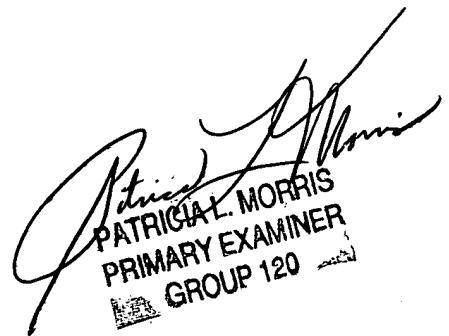
***Priority***

Applicants are requested to update the status of the parent application, Ser. No. 09/422,568, on page 1 of the specification. Cooperation herein is appreciated.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Morris whose telephone number is (703) 308-4533.



PATRICIA L. MORRIS  
PRIMARY EXAMINER  
GROUP 120

plm

May 28, 2003